K121234

510(K) SUMMARY

NOV 20 2012

Device Name:	**GORE® DrySeal Sheath with hydrophilic coating**
Proprietary Name:	GORE® DrySeal Sheath with hydrophilic coating
Common Name:	Introducer Sheath
Classification Name:	Catheter, Introducer (per 870.1340)
Device Classification:	Class II
Product Code:	DYB
Date Summary Prepared:	**April 17, 2012** **October 5, 2012, *revised***
Contact Person:	Alicia L. Hemphill, M.S., RAC

Regulatory Affairs
Medical Products Division
W. L. Gore & Associates, Inc.
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Device Description

The GORE® DrySeal Sheath consists of a hydrophilic coated introducer sheath with GORE® DrySeal Valve attached, a dilator, and a syringe.

The introducer sheath is a polyethylene tube with a tapered leading tip and marker band incorporated within the sheath material to allow identification under fluoroscopy. The sheath has an insert molded hub on the trailing end, which is attached to the GORE® DrySeal Valve.

The GORE® DrySeal Valve is comprised of an outer silicone tube and an inner film tube. The region between the silicone tube and film tube is pressurized by injecting 2.5mL of saline into the space, using the provided syringe, during procedural preparation of the device.

The dilator has a tapered leading end and provides dilatation of the access vessel. A mark on the trailing end of the dilator ensures correct positioning of the dilator within the sheath.

Device Modification

A hydrophilic coating has been added to the GORE® DrySeal Sheath. No other changes were made to the proposed device from that cleared under K093791.

Predicate Devices

GORE® DrySeal Sheath with hydrophilic coating:

GORE® DrySeal Sheath (K093791)

Indications

The GORE® DrySeal Sheath with hydrophilic coating is intended to be inserted in the vasculature to provide a conduit for the insertion of endovascular devices while minimizing blood loss associated with such insertions.

Biocompatibility

Results for all biocompatibility testing demonstrate that the materials used meet the requirements of ANSI/AAMI/ISO 10993.

Test	Test Description	Result (Pass/Fail)
Cytotoxity ISO 10993-5	MEM Assay (qualitative)	**Pass**
[1]Sensitization ISO 10993-10	Murine Local Lymph Node Assay	**Pass**
Intracutaneous Reactivity ISO 10993-10	Intracutaneous Irritation Test	**Pass**
Acute System Toxicity ISO 10993-11 ISO 10993-12	Acute Systemic Study in Mice	**Pass**
Hemocompatibility ISO 10993-4 ISO 10993-12	Complement Activation Hemolysis Assay *In vivo* Thrombogensis Prothrombin Time Assay	**Pass**
Pyrogenicity ISO 10993-11 ISO 10993-12	Rabbit Pyrogen Test	**Pass**

[1]Additional Sensitization Testing Submitted September 18, 2012

Substantial Equivalence

GORE® DrySeal Sheath, W. L. Gore & Associates, K093791. Documentation provided includes a detailed comparison which demonstrates that the proposed GORE® DrySeal Sheath hydrophilic coated introducer sheath is substantially equivalent to the predicate GORE® DrySeal Sheath cleared under K093791. A hydrophilic coating has been added to the GORE® DrySeal Sheath. No other changes were made to the introducer sheath, DrySeal Valve or dilator from that cleared under K093791.

Additionally, the following tests/evaluations were performed to confirm equivalence to the predicate device:

- Biocompatibility
- Sterilization Validations
- Packaging Integrity
- Product Shelf-Life

- Design Verification

Any differences in the technological characteristics do not raise any new issues of safety and efficacy.

The results demonstrate that the lubricity of the GORE® DrySeal Sheath with hydrophilic coating performs as designed, is suitable for its intended use, and that it is substantially equivalent to the predicate device.

Conclusion

Any differences in the technological characteristics do not raise any new issues of safety and efficacy. In terms of intended use, design, material composition and technological characteristics, the GORE® DrySeal Sheath with hydrophilic coating is substantially equivalent to the 510(k) predicate device.

Testing in Support of Substantial Equivalence Determination

Tests Performed to Establish Equivalence to Predicate Device(s)

Performance Testing	Applicable Test Standard
Lubricity	Comparative Analysis
Particulation	Comparative Analysis
Biocompatibility	ANSI/AAMI/ISO 10993-1
Sterilization Validation	ANSI/AAMI/ISO 11135-1 AAMI TIR 28
Product Expiration Dating	Gore Internal Procedures

Conclusion

The proposed device meets the performance criteria of design verification as specified by test protocols. The GORE® DrySeal Sheath with hydrophilic coating is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

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W.L. GORE & Associates, Inc.
c/o Alicia L. Hemphill
Regulatory Affairs Associate
3450 West Kiltie Lane
Flagstaff, AZ 86001

Re: K121234
Trade/Device Name: GORE® DrySeal Sheath with Hydrophilic Coating
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: November 13, 2012
Received: November 15, 2012

Dear Ms. Hemphill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either Class II (Special Controls) or Class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

Digitally signed by Matthew G. Hillebrenner
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300213272, cn=Matthew G. Hillebrenner
Date: 2012.11.20 10:48:56 -05'00'

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K121234 **TBD**

Device Name: GORE® DrySeal Sheath with hydrophilic coating

Intended Use / Indication For Use: The GORE® DrySeal Sheath with hydrophilic coating is intended to be inserted in the vasculature to provide a conduit for the insertion of endovascular devices while minimizing blood loss associated with such insertions.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121234